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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/326,402	06/04/99	BLUMENFELD M	GENSET.030A

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EXAMINER	
SIU,S	
ART UNIT	**PAPER NUMBER**
1631	11

DATE MAILED: 09/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/326,402	Applicant(s) BLUMENFELD ET AL.	
	Examiner Stephen C Siu	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-162* is/are pending in the application.

4a) Of the above claim(s) *1-120,142-149 and 153-162* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *121-141 and 150-152* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election of Group III, claims 121-141 and 150-152 in Paper No.10 is acknowledged. Claims 1-120, 142-149 and 153-162 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Because applicant did not distinctly and specifically point out any supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Objections

Claim 131 is objected to because of the following informalities: there are 2 periods at the end of the sentence. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claims 151 and 152 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 151 and 152 recite biallelic markers selected from the group consisting of "A1 to A125" or "A2, A30, A41, A55, and A57". It is not clearly recited what these numbers represent. No recitation is made as to what is being referred.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 121-126 and 150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barany (US Pat No 6027889, 2/22/00, filed 5/28/97) in view of Su (Proc. Natl. Acad. Sci., Vol.93, July 1996, pages 7252-7257).

Barany (US Pat No 6027889, 2/22/00, filed 5/28/97) discloses a method of detection of nucleic acid sequences, the method being used in the detection of human cancers such as prostate cancer and involving oncogenes, tumor suppressor genes, or genes involved in DNA amplification with polymerase chain reactions, replication, recombination or repair (col.35, lines 12-23). In one embodiment, detection of a given sequence or sequences involves selective amplification of the sequences by polymerase chain reaction (col.1, lines 62-65). The amplified sequences are then identified by a variety of techniques (col.2, lines 3-4).

Barany does not explicitly teach the identification of the nucleic acid sequences at a PCTA-1-related biallelic marker.

Su (Proc. Natl. Acad. Sci., Vol.93, July 1996, pages 7252-7257) teaches the PCTA-1 gene and its association with human prostate cancer. Su suggests direct applications for prostate cancer diagnosis and staging (page 7257, col.1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of detection of nucleic acid sequences in the detection of prostate cancer as per the teachings of Barany and to further identify the nucleic acid sequence at a PCTA-1-related site because the PCTA-1 gene is associated with human prostate cancer as per the teachings of Su. Thus, one of ordinary skill in the art would have been motivated to modify the teachings of Barany in the detection of nucleic acid sequences in prostate cancer by identifying the nucleic acid sequences at sites known to be associated with prostate cancer with a reasonable expectation of success.

Claims 121-130 and 150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barany (US Pat No 6027889, 2/22/00, filed 5/28/97) in view of Su (Proc. Natl. Acad. Sci., Vol.93, July 1996, pages 7252-7257) as applied to claims 121-126 and 150 above, and further in view of Simons (US Pat No 5612179, 3/18/97, filed 9/23/92) and Syvanen (Am. J. Hum. Genet, 1993, 52:46-59).

Barany and Su teach a method of identifying a nucleic acid as described above.

Barany and Su do not explicitly teach the method of determining the identity of a nucleotide as being a hybridization assay, sequencing assay or microsequencing assay.

Simons (US Pat No 5612179, 3/18/97, filed 9/23/92) discloses a method for detection of at least one allele of a genetic locus that can be used to provide direct determination of the haplotype. An amplified DNA sequence is analyzed to detect the presence of a genetic variation in the amplified DNA sequence, the variation is

characteristic of the allele to be detected. Primers are used that hybridizes to nucleotides of a designated regioni of the allele sequence (col.11, lines 58-61).

Syvanen (Am. J. Hum. Genet, 1993, 52:46-59) teaches a method for identification of individuals, in which a panel of biallelic DNA markers are amplified by the PCR, and the variable nucleotides are detected in the amplified DNA fragments by the solid-phase minisequencing method.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of determining the identity of a nucleotide as per the teachings of Barany and Su and to further identify the nucleic acid sequences using a hybridization assay, sequencing or microsequencing assay because such methods had been taught in the art as effective methods for identifying such nucleic acid sequences as per the teachings of Syvanen or Simons. Thus, one of ordinary skill in the art would have had the motivation to perform the claimed invention with a reasonable expectation of success.

Claims 121-126, 131-141 and 150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barany (US Pat No 6027889, 2/22/00, filed 5/28/97) in view of Su (Proc. Natl. Acad. Sci., Vol.93, July 1996, pages 7252-7257) as applied to claims 121-126 and 150 above, and further in view of Erlich (US Pat No 5110920, 5/5/92, filed 8/30/88).

Barany and Su teach a method of identifying a nucleic acid as described above.

Barany and Su do not explicitly teach computation of the proportional representation of the biallelic marker in a population, comparing with a control group, calculation of the frequency of haplotypes, or determining association with a trait.

Erlich (US Pat No 5110920) discloses a typing method based on restriction length polymorphism wherein the inclusionary probability can be calculated based on the frequency of the particular restriction fragment in the population. Genetic susceptibility to a number of diseases shows linkage as well as association in population studies with specific serologically defined variants of the HLA class I and class II loci. In one embodiment, the genetic basis of IDDM susceptibility is complex; about 70% of the genetic component is thought to be HLA-linked and the penetrance, as revealed by monozygotic twin studies, is about 50%. IDDM has been associated in population studies with the DR3 and/or DR4 specificities, about 90% of IDDM patients are either DR3 and/or DR4, compared to about 55% of control individuals.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of determining the identity of a nucleotide as per the teachings of Barany and Su and to further perform the computation of the proportional representation of the biallelic marker in a population, comparing with a control group, calculation of the frequency of haplotypes, or determining association with a trait because calculating the proportional representation of a biallelic marker in a population and determining association of a trait with the marker would provide information on the genetic susceptibility to diseases as per the teachings of Erlich.

Thus, one of ordinary skill in the art would have been motivated to perform the claimed invention with a reasonable expectation of success.

Conclusion

No claims allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stephen Siu, whose telephone number is (703) 308-7522. The Examiner can normally be reached from 7:00 a.m. to 3:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028. Papers related to this application may be submitted to Art Unit 1631 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 308-0294. Please call the Examiner at (703) 308-7522 before the transmission to expedite delivery of the fax. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stephen Siu

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER